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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,392	12/07/2001	David Ganderton	478.1011	4915

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EXAMINER

AZPURU, CARLOS A

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,392

Applicant(s)

GANDERTON ET AL.

Examiner

Carlos A. Azpuru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23, 25, 26 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 19-23, 25, 26 and 29 is/are rejected.
- 7) ☐ Claim(s) 12-18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of the preliminary amendment and information disclosure statement filed 12/07/01.

Claim Objections

Claim 26 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim fails to further limit the invention in that it depends from a method of forming amino acid particles which have been vaporized. The material to be dried is by necessity, and amino acid solution.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, 19-23, 25, 26 and 29 rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo et al (US Patent No. 6,518,239) in view of Morton et al. (Proceedings of the Aerosol Society Tenth Annual Conference, Swansea, 1996).

Kuo et al disclose an amino acid particle (see col, 3, lines 36-53; col. 5, lines 64-67; col. 6, lines 1-5. The particles have a bulk density of from about 0.1 to 10 g/cubic centimeter, which would include value of 0.05 to 0.15 in the lower range due to the use of the language "about" (see col. 13, lines 27-31). MMAD is measure as 0.1 um to 10 um, but preferably less than 4.0 um. The particles may contain several amino acids including leucine as shown at col. 8, lines 27-54. Mass median diameter is less than 10 microns (see col. 2, lines 37-39. The resultant powders are used in aerosolized administration (see Abstract). The weight percentage of the aerosolized particles contains from about 2 to about 99% of the amino acid composition. Diluents are present in amounts ranging from about 0.01% to about 95% by weight. Diluents may include several sugars (see col. 10, lines 4-6). Methods of making the powders include spray drying (see col. col. 11, lines 36-51., but also include other forms such as evaporative drying and supercritical fluid processing (col. 12, lines 23-26). Kuo does not specifically recite all aerosol condensation or gas to particle methods.

However, Morton specifically teaches that aerosol synthesis and gas to particle methods which involves forming a vapor then condensing the particles. As such the amino acid particles and method of preparing these particles would have been well within the skill of the ordinary practitioner. Indeed, the particles claimed would have a reasonable expectation of similar therapeutic results after aerosolization. There is nothing unusual and or unexpected about either the

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particles or the method of making them. As such, the instant amino acid particles having the claimed bulk density MMAD, weight percentage and method of making would have been obvious given the teachings of Kuo, and further in view of the additional methods of preparing known in the art as shown by Morton et al.

Claims 12-18 are objected to as dependent upon a rejected base claim.

WO97036049 is cited as a patent of interest in its disclosure of leucine particles. The patent lacks any teaching of bulk density characteristics.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is 703/308-0237. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

ca
August 11, 2003


CARLOS AZPURU
PRIMARY EXAMINER
GROUP 1500